K010835

busse
Hospital Disposables

APR 3 0 2001

510(k) SUMMARY

Date Prepared:
March 16, 2001

Submitter's Information:
Name: Busse Hospital Disposables
Address: 75 Arkay Drive
Hauppauge, New York 11788
Telephone: 631 435-4711
Facsimile: 631 435-9403
Contact: Vicki Ator

Trade Name, Common Name, Classification:
The device trade name is Busse Hospital Disposables' Posi-Grip ™ Umbilical Cord Clamp. The device common name is umbilical cord clamp. It is a class II device (CFR 21 884.4550).

Predicate Device:
Busse identifies the following device as a predicate:

- Hollister® Double Grip® Umbilical Cord Clamp(K781548)

Description of the Device:
The Posi-Grip ™ Umbilical Cord Clamp is a disposable nylon V-shaped device designed with double gripping surfaces to compress rather than cut the umbilical cord and to maintain firm pressure preventing blood loss as the cord dries and shrinks after birth.

Intended Use:
The intended use of the device is to close off the newborn's umbilical cord and prevent blood loss as the cord dries and shrinks after birth.

Technological Characteristics:
The subject device is composed of the same generic material as the Hollister clamp. The intended use, design, and manufacture are the same. Additionally, similar packaging and sterilization methods are to be utilized.

Performance Data:
Busse's functional evaluations included a comparative closure force test, a leak test and a cold temperature breakage test.

Biocompatibility testing (Cytotoxicity and Sensitization) was performed on the device with favorable results.

When tested for EtO residuals the umbilical cord clamps showed safe levels according to FDA 1978 Guidelines and current ANSI/AAMI/ISO requirements.

Conclusion:
Busse concludes that the subject device is as safe and effective as the predicate device and poses no new questions for safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2001

Ms. Vicki Ator
Quality Manager
Busse Hospital Disposables, Inc.
75 Arkay Drive
HAUPPAUGE NY 11788

Re: K010835
Busse Posi-Grip™ Umbilical Cord Clamp
Model 384 (sterile) and Model 385 (non-sterile)
Dated: March 19, 2001
Received: March 20, 2001
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HFW

Dear Ms. Ator:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010835

Device Name: Busse Hospital Disposables' Posi-Grip Umbilical Cord Clamp

Indications For Use: The Umbilical Cord Clamp is indicated for use following a live birth. It provides a means of constricting the umbilical cord in order to prevent loss of blood as the cord dries and shrinks after birth. It is used immediately following delivery of the infant and prior to the separation of the umbilical cord between mother and infant.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010835

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)